IX. 510(k) Summary of Safety and Effectiveness

JAN 31 2002

SUBMITTER: Boston Scientific Target
47900 Bayside Parkway
Fremont, CA 94538

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DATE PREPARED: August 28, 2001

CLASSIFICATION NAME: Artificial Embolization Device
(21 CFR Section 882.5950)

COMMON NAME: Occlusion Coil

PROPRIETARY NAME: Matrix™ Detachable Coils

PREDICATE DEVICE: Guglielmi Detachable Coil (GDC™) and GDC™ Power Supply (K001083)

DEVICE DESCRIPTION: The Matrix™ Detachable Coil system consists of the following, each of which is sold seperately:

- GDC™ SynerG™ Power Supply
- Matrix™ Detachable Coil attached to a delivery wire
- Set of GDC™ SynerG™ connecting cables
- Patient return electrode
- Two 9-volt batteries

The coil is detached by electrolytically dissolving a small portion of the delivery wire upon desired placement of the coil in the anatomy.

Matrix™ Detachable Coils are manufactured from platinum wire, which is first wound into a primary coil and then formed into a secondary helical shape. Coating the platinum coil is a proprietary biocompatible absorbable polymer mixture.

Coils are attached to a delivery wire, which consists of a ground stainless-steel core wire with a stainless-steel coil welded at the distal end and a Teflon® outer jacket. The delivery wire is identical to that employed for the predicate GDC™ Coils cleared under K001083.

The GDC™ SynerG™ power supply is a battery-operated, self-contained unit designed to initiate and control the electrolytic detachment of a GDC™ Coil or Matrix™ Detachable Coil inside an aneurysm.

Each time the power supply is turned on, the unit defaults to the 1.0 mA current setting. Pressing the "Current" switch one time changes the setting to the 2.0 mA current setting; pressing a second time changes the setting to 0.5 mA; pressing a third time returns the unit to the default 1.0 mA setting. Each time the switch is pressed, the current display flashes the new current setting.

The GDC™ SynerG™ Power Supply is designed to apply a constant current through the GDC™ System and to detect when coil detachment has occurred. It maintains a constant current by:

1) sensing the amount of resistance to current flow through the Matrix™ Detachable Coil, and
2) adjusting the voltage needed to maintain the desired current setting. It is also designed to identify subtle changes in the way current is flowing through the Matrix™ Detachable Coil and to recognize those changes, which indicate detachment.

Once those patterns are identified, the GDC™ SynerG™ power supply signals detachment and stops the flow of current through the Matrix™ Detachable Coil.

INTENDED USE:

Matrix™ Detachable Coils are intended for embolizing certain intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolizing other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature.

Matrix™ Detachable Coils are also intended for arterial and venous embolizations in the peripheral vasculature.

MATERIALS:

All component materials of the Matrix™ Detachable Coils are biocompatible in accordance with ISO 10993-1.

TECHNOLOGICAL CHARACTERISTICS COMPARISON:

Coil Dimensional Attributes	Matrix™ Detachable Coils
Coil Primary Wind OD (Platinum alloy and Polymer)	Same as predicate device.
Secondary Coil OD	Same as predicate device.
Coil Wire OD	Same as predicate device.
Delivery Wire Length	Same as predicate device.
Delivery Wire Proximal OD	Same as predicate device.
Delivery Wire Distal OD	Same as predicate device.

Technological Characteristics Comparison (cont.):

Materials	Matrix™ Detachable Coils
Main Coil	
Main Coil Wire	Same as predicate device (The Matrix™ detachable Coils additionally incorporate a biocompatible absorbable polymer and ultraviolet curing adhesive in the Main Coil.)
Main Coil / delivery wire junction tubing	Same as predicate device
Delivery Wire	
Core wire w/coating	Same as predicate device
Proximal Coil	Same as predicate device
Proximal Marker Coil	Same as predicate device
Sheath, Delivery Wire (heat shrink tubing)	Same as predicate device
Proximal Tubing	Same as predicate device
Bushing	Same as predicate device
Inner Coil	Same as predicate device

Technological Characteristics Comparison (cont.):

Power Supply	Matrix™ Detachable Coils
Power	Same as for predicate device.
Batteries	Same as for predicate device.
Expected Battery Life	Same as for predicate device.
Red Cable	Same as for predicate device.
Black Cable	Same as for predicate device.
Current Settings	Same as for predicate device.
Current	Same as for predicate device.
Voltage	Same as for predicate device.
Operating Temp.	Same as for predicate device.
Storage Temp.	Same as for predicate device.
Relative Humidity	Same as for predicate device.
Unit Size	Same as for predicate device.
Unit Weight	Same as for predicate device.

Verification Test Summary Table:
Predicate GDC™ Coils vs Matrix™ Detachable Coils

Test or Point of Comparison	Matrix™ Detachable Coils
Friction	Meets acceptance criteria established for predicate device.
Catheter / Coil Compatibility	Meets acceptance criteria established for predicate device.
Main Coil Tensile Strength	No change made which would affect this test.
Main Coil Junction Strength	Meets acceptance criteria established for predicate device.
Coil Stiffness Test	Meets acceptance criteria established for predicate device.
Coil Stability in Aneurysm Test	Meets acceptance criteria established for predicate device.
Polymer Mass Loss Tests	Meets acceptance criteria established for device.
Deployment / Retraction Test	Meets acceptance criteria established for device.
Polymer to Platinum Bond Integrity Testing	Meets acceptance criteria established for device.
Polymer Integrity Tensile Strength Test	Meets acceptance criteria established for device.
Compatibility with Saline Test	Meets acceptance criteria established for device.
Detachment Time	No change made which would affect this test.
Heating Effect of Electrolysis	No change made which would affect this test.
Heating Effect of MRI	No change made which would affect this test.
Electrostatic Discharge	No change made which would affect this test.
Electromagnetic Compatibility-Radiated Susceptibility	No change made which would affect this test.
Electromagnetic Compatibility-Radiated Emissions Class B	No change made which would affect this test.
Electromagnetic Compatibility-Magnetic Immunity	No change made which would affect this test.
Operating System Test (Assembly Source Code)	Meets acceptance criteria established for predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2002

Mr. Seth A. Schulman
Senior Regulatory Affairs Specialist
Boston Scientific, Target
47900 Bayside Parkway
Fremont, California 94538

Re: K012985
Trade/Device Name: Matrix™ Detachable Coil
Regulation Number: 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: III
Product Code: HCG
Dated: December 12, 2001
Received: December 14, 2001

Dear Mr. Schulman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IX. 510(k) Summary of Safety and Effectiveness

510(k) Number (if known): K012985

Name: Matrix™ Detachable Coil

Indications For Use:

The Matrix™ Detachable Coils have the same indications for use as the predicate GDC™ coils.

Matrix™ Detachable Coils are intended for embolization of those intracranial aneurysms that - because of their morphology, their location, or the patient's general medical condition - are considered by the treating neurosurgical team to be:

a) very high risk for management by traditional operative techniques, or,
b) inoperable,

and for embolization of other neuro vascular abnormalities such as arteriovenous malformations and arteriovenous fistulae.

The Matrix™ Detachable Coils are also intended for arterial and venous embolizations in the peripheral vasculature.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use:_____
(Per 21 CFR §801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012985